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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KOSAR, ANDREW D	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 07/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/632,366	COOPER ET AL.	
	Examiner	Art Unit	
	Andrew D. Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) *32-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/12/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group III, claims 13-18, and the species SEQ ID NO:1, in the reply filed on April 24, 2006 is acknowledged. The traversal is on the ground(s) that Applicant asserts there is no undue burden to examine all of the claims and further asserts that the restriction is improper because the examiner does not provide "concrete reasons" why the groups are independent and/or distinct and further asserts that the rationale provided for burden is missing. Applicant further asserts that there would be no burden because, "Applicants believe preptin to be a previous unknown and uncharacterized, pancreatic islet beta-cell hormone." (page 6).

This is not found persuasive because the examiner has set forth a proper *prima facie* case for restriction. As stated previously, the patient populations for each group is different and do not overlap (mutually exclusive), such that in practicing one method one would be practicing another (not obvious variants) as each has a different desired outcome (mode of operation/function/effect). Contrary to Applicant's position, this satisfies the requirement of the three-fold test Applicant sets forth on page 4 of the response.

With regards to burden, the examiner set forth a proper statement of burden indicating that the NPL search would not be coextensive for the various claimed methods. Further,, Applicant is incorrect in asserting that there would be no burden because preptin is "previous unknown and uncharacterized" hormone. Preptin has, in fact, been previously characterized, as evidenced by the citation of WO 00/78805 A1 (COOPER and BUCHANAN) which clearly and unambiguously shows preptin and analogs and methods of use.

It is noted that the examiner inadvertently identified claims 62 and 63 as 'increasing insulin secretion' which should read 'promoting growth of tissues'. This does not alter the groupings of the claims.

However, Upon review of the prior art, the examiner has REJOINED Groups II-V (claims 1-31), as it has been found that in practicing the method of Group V, for example, one would inherently be practicing the method of Group III.

The requirement is still deemed proper and is therefore made FINAL.

Claims 32-65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 24, 2006.

Claims 1-31 have been examined on the merits.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in New Zealand on August 1, 2002. It is noted, however, that applicant has not filed a certified copy of the 520536 application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

The information disclosure statement filed August 12, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered for references which have been 'crossed through'.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

Claim 25 is objected to because of the following informalities: the claim recites '□' rather than 'β'. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107

F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art*, (2) *partial structure*, (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention.*

In the instant case, the claims are drawn to methods of treating a condition characterized by or involving, or that may be relieved in any measure by ameliorating, decreased β-cell mass and/or number, increasing β-cell mass and/or number and increasing insulin secretion via administration of preptin or an analog, derivative or salt, or a preptin agonist:

(1) Level of skill and knowledge in the art:

Preptin is known in the art (e.g. WO 00/78805 A1) and is taught to be used to treat diabetes.

(2) Partial structure:

The specification and art provide the structure of preptin, however the specification provides only that the agonist is a fragment of preptin and does not disclose any other structures to describe the myriad of compounds that may have the function claimed.

Dependent claims state that the agonist is a fragment and alternatively that the agonist has 60, 80, 90 or 95 % identity with preptin of SEQ ID NOs:1-3, or has conservative substitutions for up to 14, 10-13, 6-9 or 2-5 amino acids, though it does not relate any specific structure necessary to perform the claimed method,.

(3) Physical and/or chemical properties and (4) Functional characteristics:

The compound must act as a preptin agonist in the methods as claimed.

(5) Method of making the claimed invention:

The specification provides how one would test a compound to determine if it has preptin agonist activity (page 5, 2nd paragraph) but does not describe any compounds determined by the method.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that the claims are broad generics, with respect to all possible compounds encompassed by the claims. Please note, claims drawn to preptin sequences have been included because they do not specifically require that, e.g., SEQ ID NO:1 be selected, but merely identify a subset for 'preptins'. The possible structural variations are limitless to any peptide or non-peptide. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. Here, though the claims may recite some functional characteristics, e.g. agonists, analogs, derivatives, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of derivatives. While having written description of preptins of SEQ ID NOs:1-3, the specification is void of a sufficient variety of peptides or organic molecules with the functional characteristics claimed.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claims 1-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating diabetes, increasing insulin secretion or stimulating β-cell growth and increasing β-cell mass and/or number via administration of preptin (SEQ ID NOs:1-3), does not reasonably provide enablement for treatment of all conditions characterized by or involving, or that may be relieved in any measure, decreased β-cell mass and/or number, or treating a mediated disease, disorder, or condition mediated in whole or in part by β-cells dysfunction, nor does it provide enablement for practicing any of the claimed methods with any agonist, derivative or analog of any preptin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to pracitce the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (Wands, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (Wands, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The instant claims are described *supra*, and in one aspect include administering preptin or its analogs, derivatives or agonists to treat any of a myriad of unidentified conditions which are characterized by or involve or that may be relieved by ameliorating, decrease β-cell mass and/or

number or a disease mediated by β-cells. The art recognizes that β-cells are generally associated with Types 1 and 2 diabetes. The breadth of the claims imply that one could treat any of the conditions resulting from diabetes, e.g. renal diseases, retinopathy, neuropathy, erectile dysfunction, hypertension and cardiovascular disease. In a second aspect, the claims are drawn to practicing the methods with any of a myriad of compounds including preptin, fragment, analogs, derivatives and agonist.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

The art recognizes the link between administration of preptin and treating diabetes.

With regards to the effect of amino acid substitution in a peptide or protein, the art is unpredictable.

RUDINGER (J. Rudinger. In: Peptide Hormones, JA Parsons, Ed. (1976) 1-7) teaches that, "The significance of particular amino acids and sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study." (Page 6).

MATHISON (US Patent 6,586,403 B1) teaches that "Restriction on the amino acid substitutions that are tolerated in analogues of FEG/feG are described [...] although a theory for the rational substitution of amino acids in to the peptides that permits the prediction of biological activity of specific peptides is not apparent. For example, it is not obvious which aromatic or aliphatic substitutions in position 1 of tri- or dipeptides would possess biological activity in the four assays examined" (column 12, lines 22-30).

Further, MPEP § 2144.08 states, "The effect of a conservative substitution on protein function depends on the nature of the substitution and its location in the chain. Although at some

locations a conservative substitution may be benign, in some proteins only one amino acid is allowed at a given position. For example, the gain or loss of even one methyl group can destabilize the structure if close packing is required in the interior domains. James Darnell *et al.*, *Molecular Cell Biology* 51 (2d ed. 1990)."

Further, the effects of a single amino acid substitution can have substantial effects on proteins in structure and/or function and are exemplified by the difference between hemoglobin (Hb) and abnormal hemoglobins, such as sickle-cell hemoglobin (HbS). VOET (D. Voet and J.G. Voet. Biochemistry, 2nd Edition.(1995), pages 235-241) teaches that the mutant hemoglobin HbE [Glu B8(26)β → Lys] has, "no clinical manifestations in either heterozygotes or homozygotes." (Page 235). Further, Hb Boston and Hb Milwaukee both have single point mutations which result in altered binding affinity and ineffective transfer from the Fe(III) to Fe(II) oxidation state. Conversely, a single point mutation in Hb Yakima results in increased oxygen binding by the heme core, and in Hb Kansas, the mutation causes the heme center to remain in the T state upon binding oxygen (rather than structurally rearranging to the R state). (Page 236).

HbS is a single point mutation, Val → Glu A3(6)β (Page 236), which results in deformation and rigidity of the red blood cell. The mutation also provides protection against most malarial strains.

Further, SMILEK (D.E. Smilek, *et al.* Proc. Natl. Acad. Sci. USA (1991) 88, pages 9633-9637) teaches that a single amino acid substitution in the myelin basic protein peptide, "confers the capacity to prevent rather than induce EAE even after peptide-specific encephalitogenic T-cells have been activated." (Abstract).

MESSER (W.S. Messer, "Vasopressin and Oxytocin", web document updated 4/3/2000; <http://www.neurosci.pharm.utoledo.edu/MBC3320/vasopressin.htm>; 5 pages) that two compounds, vasopressin [cyclo(1-6)CY**I**QNCP**L**G-NH_2] and oxytocin [cyclo(1-6)CY**F**QNCP**R**G-NH_2] differ by only two amino acids, as indicated, yet they have different functions. Vasopressin (antidiuretic hormone, ADH), "at low doses controls the resorption of water by the distal tubules of the kidneys and regulates the osmotic content of blood... [and at] high doses, ADH causes contraction of arteriles (*sic*) and capillaries, especially those of the coronary vessels, to produce localized increases in blood pressure." (page 1). Oxytocin, on the other hand, stimulates smooth muscle contraction in the uterus, mammary glands, and the "alveoli and larger sinuses of the mammary glands to make readily available milk" (page 1). Further, ADH has 2 types of receptors (V1 and V2) found in vascular smooth muscle and the kidney, while oxytocin has one type of receptor found in uterine and mammary smooth muscle.

RUDIKOFF (S. Rudikoff, et al. Proc. Natl. Acad. Sci. USA (1982) 79, pages 1979-1983) teaches that, "To date, it is not known whether the limited number of amino acid substitutions presumably generated by somatic mutation can be effective in altering antigen binding specificity or affinity" (page 1979) and further teach that, "...a single amino acid substitution is capable of completely altering antigen-binding specificity." (page 1982).

Thus, because there is a significant gap in the knowledge in the art with regards to predicting *a priori* the effect of substitution on the function of the resulting peptide and because even small changes in proteins and peptides can produce highly divergent and unpredictable results in a variety of systems, the art is considered highly unpredictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is low, given the high unpredictability in the art.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided examples of using preptin to show growth/differentiation of a β-cell model system using thymidine uptake studies. However, the specification does not provide treatment of any condition characterized by or involving, or that may be relieved in any measure by ameliorating or mediated by β-cells or β-cell dysfunction beyond that of treating diabetes, with preptin, which is known in the art. The specification provides no examples of using any other compound to show cellular growth beyond that of preptin.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above and the high unpredictability and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims without undue experimentation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-31 are rejected under 35 U.S.C. 102(b) as being anticipated by COOPER (WO 00/78805 A1; PTO-1449, 8/12/04).

The instant claims are presented *supra*.

Cooper teaches a method of therapeutically or prophylactically treating a patient (claim 33), stimulating insulin secretion for a therapeutic or prophylactic purpose (claim 34), treating type 2 diabetes (claim 35), or treating a condition which results in or involves deficient insulin synthesis, secretion or action (claim 36), which comprises the step of administering a preptin or preptin analog or salt. Instant SEQ ID NO:1 is specifically embodied in Cooper (claim 3) as a species used in practicing the methods.

In practicing the method of Cooper, one is inherently practicing the instant methods of increasing β-cell count and/or number and stimulating β-cell growth as the same compound is being administered to the same patient populations. Further, diabetes is a disease mediated by/involving β-cells dysfunction, and therefore number of functional cells.

Because all people are 'in need thereof' of maintenance of β-cell count to prevent diabetes, the prophylactic administration in Cooper anticipates the instant methods of increasing β-cell number/mass and stimulating β-cell mass/growth.

Additionally, because the dependent claims merely limit the scope of one aspect of the Markush group base claim, but do not specifically require the selection of the element or preclude the selection of preptin, the teachings of Cooper anticipate the dependent claims. Furthermore, preptin administration anticipates all 'at least about' limitations, as it is 100% identical to SEQ ID NO:1 and because it is not required 'up to about' 14 conservative amino acid substitutions includes no conservative substitutions.

Claims 1-31 are rejected under 35 U.S.C. 102(b) as being anticipated by XU (G. Xu,, et al. Diabetes (1999) 48(12), pages 2270-2276).

Xu teaches administration of Exendin-4 to diabetic rats resulting in increasing β-cell number (replication and neogenesis) and β-cell mass (*throughout*, e.g. Abstract, Title).

Exendin is a functional analog, as it functions as preptin instantly claimed. Because the dependent claims merely limit the scope of one aspect of the Markush group base claim (agonist or preptin), but do not specifically require the selection of the element or preclude the selection of analogs, the teachings of Xu anticipate the dependent claims.

Claims 1-31 are rejected under 35 U.S.C. 102(e) as being anticipated by COOPER (US 2003/0166561 A1; PTO-1449, 8/12/04).

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the

inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The instant claims are presented *supra*.

Cooper teaches a method of therapeutically or prophylactically treating a patient (claim 50), stimulating insulin secretion for a therapeutic or prophylactic purpose (claim 56), treating type 2 diabetes (claim 62), or treating a condition which results in or involves deficient insulin synthesis, secretion or action (claim 68), which comprises the step of administering a preptin or preptin analog or salt. Instant SEQ ID NO:1 is specifically embodied in Cooper (claim 3) as a species used in practicing the methods.

In practicing the method of Cooper, one is inherently practicing the instant methods of increasing β-cell count and/or number and stimulating β-cell growth as the same compound is being administered to the same patient populations. Further, diabetes is a disease mediated by/involving β-cells dysfunction, and therefore number of functional cells.

Because all people are 'in need thereof' of maintenance of β-cell count to prevent diabetes, the prophylactic administration in Cooper anticipates the instant methods of increasing β-cell number/mass and stimulating β-cell mass/growth.

Additionally, because the dependent claims merely limit the scope of one aspect of the Markush group base claim, but do not specifically require the selection of the element or preclude the selection of preptin, the teachings of Cooper anticipate the dependent claims. Furthermore, preptin administration anticipates all 'at least about' limitations, as it is 100% identical to SEQ ID NO:1 and because it is not required 'up to about' 14 conservative amino acid substitutions includes no conservative substitutions.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 50-73 of copending Application No. 10/374,624. Although the conflicting claims are not identical, they are not patentably distinct from each other because as set forth above under 35 USC § 102(e), in practicing the methods of Cooper, one is inherently practicing the instantly claimed method as one is administering the same compound to the same patient population.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-31 are directed to an invention not patentably distinct from claims 50-73 of commonly assigned 10/374,624 (COOPER, *supra*), for the reasons set forth above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300).

Commonly assigned 10.374,624, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Conclusion

NO CLAIMS ARE ALLOWED.

The prior art made of record on the attached PTO-892 and not relied upon in any rejection is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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